

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

I hereby declare the application of: John S. PATTON, et al.)

Atty. Docket No.: 0005.15

Examiner: Gollamudi S. KISHORE

Application No.: 10/612,376

Group Art Unit: 1615

Filed: July 1, 2003

Title: METHODS AND COMPOSITIONS
FOR PULMONARY DELIVERY OF
INSULIN

CERTIFICATE OF MAILING

I hereby certify that this correspondence is being deposited with the United States Postal Service as First Class Mail in an envelope addressed to: Commissioner for Patents, P.O. Box 1450 Alexandria, Virginia 22313-1450 on April 12, 2006

Signed: Mina Cotter

SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT

UNDER 37 CFR §1.56, §1.97 and §1.98

Commissioner for Patents
P.O. Box 1450
Alexandria, Virginia 22313-1450

Dear Sir:

The references listed in the attached Forms PTO/SB/08A and B may be material to examination of the above-identified patent application. Applicants submit these references in compliance with their duty of disclosure pursuant to 37 CFR §§1.56, 1.97, and 1.98. The Examiner is requested to make these citations of official record in this application.

This Information Disclosure Statement is not to be construed as a representation that a search has been made, that additional information material to the examination of this application does not exist, or that these references indeed constitute prior art.

In compliance with 37 CFR §§1.98 enclosed are copies of each foreign patent, each publication or that portion which caused it to be listed, other than U.S. patents and U.S. patent application publications unless required by the Office.

Attorney Docket No. 0005.15

04/19/2006 SFELEKE1 00000004 500348 10612376
02 FC:1464 130.00 DA

This Information Disclosure Statement is being timely filed under 37 CFR §§1.97 and is being filed:

☒ within three months of the filing date of a national application or an RCE; within three months of the date of entry of the national stage as set forth in section 1.491 in an international application; or before the mailing date of a first Office action on the merits (whichever event occurs last)

☐ Please charge the amount of \$130 to Deposit Account 500348

☒ If it is determined that any additional fees are due, the Commissioner is hereby authorized to charge such fees to Deposit Account 500348.

Respectfully submitted,

NEKTAR THERAPEUTICS

Dated: 12 APR 2006

By:



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Reg. No. 45,302

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Form PTO/SB/08A (Modified) Information Disclosure Statement By Applicant <i>(Use Several Sheets if Necessary)</i>	Atty Docket No.: 0005.15	Application No.: 10/612,376
	Applicant: John S. Patton, et al.	
	Filing Date: 07/01/2003	Group: 1615

U.S. Patent Documents

Examiner Initial		Patent No.	Date	Patentee	Class	Sub-Class	Filing Date
	1	2002/0127188	09/2002	Platz et al.			
	2	2002/0132787	09/2002	Eljamal et al.			
	3	2002/0192164	12/2002	Patton et al.			
	4	2003/0035778	02/2003	Platz et al.			
	5	2003/0068279	04/2003	Platz et al.			
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	8	2003/0092666	05/2003	Eljamal et al.			
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	10	2003/0113900	06/2003	Tunnacliffe et al.			
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	13	2003/0198601	10/2003	Platz et al.			
	14	2003/0203036	10/2003	Gordon et al.			
	15	2003/0215512	11/2003	Foster et al.			
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	22	2005/0186143	08/2005	Stevenson et al.			
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	24	979,993	12/1910	O'Byrne et al.			
	25	3,555,717	01/1971	Chivers			
	26	3,619,294	11/1971	Black et al			
	27	3,632,357	01/1972	Childs			
	28	3,655,442	04/1972	Schwer, et al.			
	29	1,855,591	04/1932	Wallenstein			
	30	3,745,682	07/1973	Waldeisen			

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Examiner: Initial citation considered. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

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	31	3,948,263	04/1976	Drake, Jr. et al.			
	32	4,102,999	07/1978	Umezawa et al.			
	33	4,127,502	11/1978	Li Mutti et al.			
	34	4,127,622	11/1978	Watanabe et al.			
	35	4,158,544	06/1979	Louderback			
	36	4,159,319	06/1979	Bachmann et al.			
	37	4,180,593	12/1979	Cohan			
	38	4,244,949	01/1981	Gupta			
	39	4,326,524	04/1982	Drake, Jr. et al.			
	40	4,327,076	04/1982	Puglia et al.			
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	42	4,371,557	02/1983	Oppy et al.			
	43	4,407,786	10/1983	Drake et al.			
	44	4,588,744	05/1986	McHugh			
	45	4,591,552	05/1986	Neurath			
	46	4,613,500	09/1985	Suzuki et al.			
	47	4,620,847	11/1986	Shishov et al.			
	48	4,680,027	07/1987	Parsons et al.			
	49	4,684,719	08/1987	Nishikawa et al.			
	50	4,701,417	10/1987	Portenhauser et al.			
	51	4,713,249	12/1987	Schroder et al.			
	52	4,719,762	01/1988	Osabe			
	53	4,721,709	01/1988	Seth et al.			
	54	4,739,754	04/1988	Shaner			
	55	4,758,583	07/1988	Cerami et al.			
	56	4,761,400	08/1988	Doat et al.			
	57	4,762,857	08/1988	Bollin, Jr. et al.			
	58	4,790,824	12/1988	Morrow et al.			
	59	4,793,997	12/1988	Drake et al.			
	60	4,812,444	03/1989	Mitsubishi et al.			

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	61	4,814,436	03/1989	Shibata et al.			
	62	4,847,079	07/1989	Kwan			
	63	4,855,326	08/1989	Fuisz			
	64	4,861,627	08/1989	Mathiowitz et al.			
	65	4,865,871	09/1989	Livesey et al.			
	66	4,866,051	09/1989	Hunt			
	67	4,883,762	11/1989	Hoskins			
	68	4,906,463	03/1990	Cleary et al.			
	69	4,988,683	01/1991	Corbiere			
	70	5,013,557	05/1991	Tai			
	71	5,026,772	06/1991	Kobayashi et al.			
	72	5,043,165	08/1991	Radhakrishnan			
	73	5,059,587	10/1991	Yamamoto			
	74	5,089,181	02/1992	Hauser			
	75	5,112,596	05/1992	Malfroy-Camine			
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	77	5,160,745	11/1992	DeLuca et al.			
	78	5,173,298	12/1992	Meadows et al.			
	79	5,182,097	01/1993	Byron et al.			
	80	5,202,333	04/1993	Berger et al.			
	81	5,215,079	05/1993	Fine et al.			
	82	5,239,993	08/1993	Evans			
	83	5,240,712	08/1993	Smith			
	84	5,240,843	08/1993	Gibson et al.			
	85	5,240,846	08/1993	Collins et al.			
	86	5,270,048	12/1993	Drake			
	87	5,284,656	02/1994	Platz et al.			
	88	5,306,506	04/1994	Zema et al.			
	89	5,312,335	05/1994	McKinnon et al.			
	90	5,312,909	05/1994	Driessen et al.			

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	92	5,348,852	09/1994	Bonderman			
	93	5,366,734	11/1994	Hutchinson			
	94	5,380,473	01/1995	Bogue et la.			
	95	5,387,431	02/1995	Fuisz			
	96	5,403,861	04/1995	Goldwin et al.			
	97	5,404,871	04/1995	Goodman et al.			
	98	5,422,360	06/1995	Miyajima et al.			
	99	5,422,384	06/1995	Samuels et al.			
	100	5,425,951	06/1995	Goodrich, Jr. et al.			
	101	5,453,514	09/1995	Niigata et al.			
	102	5,512,547	04/1996	Johnson et al.			
	103	5,518,709	05/1996	Sutton et al.			
	104	5,547,696	08/1996	Sorensen			
	105	5,571,499	11/1996	Hafler et al.			
	106	5,580,859	12/1996	Felgner et al.			
	107	5,567,439	10/1996	Myers et al.			
	108	5,589,167	12/1996	Cleland et al.			
	109	5,591,453	01/1997	Ducheyne et al.			
	110	5,607,915	03/1997	Patton			
	111	5,611,344	03/1997	Bernstein et al.			
	112	5,618,786	04/1997	Roosdorp et al.			
	113	5,631,225	05/1997	Sorensen			
	114	5,621,094	04/1997	Roser et al.			
	115	5,642,728	07/1997	Andersson et al.			
	116	5,654,278	08/1997	Sorensen			
	117	5,681,746	10/1997	Bodner et al.			
	118	5,728,574	03/1998	Legg			
	119	5,705,482	01/1998	Christensen et al.			
	120	5,707,352	01/1998	Sekins			

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	121	5,733,555	03/1998	Chu			
	122	5,766,520	06/1998	Bronshtein			
	123	5,775,320	07/1998	Patton et al.			
	124	5,780,014	07/1998	Eljamal et al.			
	125	5,780,295	07/1998	Livesey et al.			
	126	5,849,700	12/1998	Sorensen et al.			
	127	5,851,453	12/1998	Hanna et al.			
	128	5,891,873	04/1999	Colaco et al.			
	129	5,928,469	07/1999	Franks et al.			
	130	5,948,411	09/1999	Koyama et al.			
	131	5,955,448	09/1999	Calaco et al.			
	132	5,792,366	10/1999	Haynes et al.			
	133	5,976,436	11/1999	Livesley et al.			
	134	5,993,783	11/1999	Eljamal et al.			
	135	5,993,805	11/1999	Sutton et al.			
	136	5,994,314	11/1999	Eljamal et al.			
	137	6,013,638	01/2000	Crystal et al.			
	138	6,034,080	03/2000	Colaco et al.			
	139	6,060,069	05/2000	Hill et al.			
	140	6,071,428	06/2000	Franks et al.			
	141	6,077,543	06/2000	Gordon et al.			
	142	6,123,924	09/2000	Mistry et al.			
	143	6,123,936	09/2000	Platz et al.			
	144	6,136,346	10/2000	Eljamal et al.			
	145	6,138,668	10/2000	Patton et al.			
	146	6,142,216	11/2000	Lannes			
	147	6,165,463	12/2000	Platz et al.			
	148	6,187,344	02/2001	Fljamel			
	149	6,190,859	02/2001	Putnak et al.			
	150	6,231,851	05/2001	Platz et al.			

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	151	6,290,991	09/2001	Roser et al.			
	152	6,258,341	07/2001	Foster et al.			
	153	6,303,581	10/2001	Pearlman			
	154	6,303,582	10/2001	Eljamel et al.			
	155	6,309,671	10/2001	Foster et al.			
	156	6,313,102	11/2001	Colaco et al.			
	157	6,331,310	12/2001	Roser et al.			
	158	6,334,182	02/2002	Sutton et al.			
	159	6,358,530	03/2002	Eljamal et al.			
	160	6,365,190	04/2002	Gordon et al.			
	161	6,372,258	04/2002	Platz et al.			
	162	6,423,334	07/2002	Brayden et al.			
	163	6,423,344	07/2002	Platz et al.			
	164	6,426,210	07/2002	Franks et al.			
	165	6,468,782	10/2002	Tunnacliffe et al.			
	166	6,479,049	11/2002	Platz et al.			
	167	6,503,411	01/2003	Franks et al.			
	168	6,509,006	01/2003	Platz et al.			
	169	6,514,496	02/2003	Platz et al.			
	170	6,518,239	02/2003	Kuo et al.			
	171	6,565,841	05/2003	Niven et al.			
	172	6,565,871	05/2003	Roser et al.			
	173	6,569,406	05/2003	Stevenson et al.			
	174	6,569,458	05/2003	Gombotz et al.			
	175	6,572,893	06/2003	Gordon et al.			
	176	6,586,006	07/2003	Roser et al.			
	177	6,589,560	07/2003	Foster et al.			
	178	6,737,045	05/2004	Patton et al.			
	179	6,592,904	07/2003	Platz et al.			
	180	6,630,169	10/2003	Bot et al.			

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Foreign Patent or Published Foreign Patent Application

Examiner Initial	No.	Document No.	Publication Date	Country or Patent Office	Class	Sub- class	Translation Yes No	
	192	1080265	04/1960	DE				
	193	3713326	10/1987	DE				
	194	0090356	10/1983	EP				
	195	0136030	04/1985	EP				
	196	0139286	05/1985	EP				
	197	0222313	05/1987	EP				
	198	0251631	01/1988	EP				
	199	0257956	03/1988	EP				
	200	0282179	09/1988	EP				
	201	0315875	05/1989	EP				
	202	0325936	08/1989	EP				
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	211	0714905	06/1996	EP				
	212	2238476	02/1975	FR				
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	215	62-228272	10/1987	JP (abstract)				
	216	62-255434	11/1987	JP (abstract)				
	217	62267238	11/1987	JP (abstract)				
	218	02084401	03/1990	JP (abstract)				
	219	03264537	11/1991	JP (abstract)				
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	221	0821036	09/1959	UK				

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Examiner Initial	No.	Document No.	Publication Date	Country or Patent Office	Class	Sub- class	Translation Yes No
	222	1381588	01/1975	UK			
	223	1533012	11/1978	UK			
	224	2187191	09/1987	UK			
	225	87/02038	04/1987	WO			
	226	88/08298	11/1988	WO			
	227	89/06976	08/1989	WO			
	228	89/09614	10/1989	WO			
	229	90/11756	10/1990	WO			
	230	91/18091	11/1991	WO			
	231	92/02133	02/1992	WO			
	232	92/18164	10/1992	WO			
	233	92/19243	11/1992	WO			
	234	93/02834	02/1993	WO (abstract)			
	235	93/10758	06/1993	WO			
	236	93/11746	06/1993	WO (abstract)			
	237	93/12240	06/1993	WO			
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	239	93/17663	09/1993	WO			
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	241	93/23110	11/1993	WO			
	242	94/07514	04/1994	WO			
	243	94/13271	06/1994	WO			
	244	94/22423	10/1994	WO			
	245	94/24263	10/1994	WO			
	246	95/01324	01/1995	WO			
	247	95/06126	03/1995	WO			
	248	95/20979	08/1995	WO			
	249	95/24183	09/1995	WO			
	250	95/31479	11/1995	WO			
	251	95/33488	12/1995	WO			

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Other Documents

Examiner Initial	No.	Author, Title, Date, Place (e.g. Journal) of Publication
	265	ADJEI, et al., "Pulmonary delivery of therapeutic peptides and proteins", J. Controlled Release, <u>29</u> :361-373, (1994)
	266	Advertisement for "Stop'n Grow" Manufactured by The Mentholatum Co. Ltd., East Kilbride Scotland G74 5P3
	267	AGRIMI, et al., "Amyloid, Amyloid-Inducers, Cytokines and Heavy Metals in Scrapie and Other Human and Animal Subacute Spongiform Encephalopathies: Some Hypotheses", Med. Hypotheses, <u>40</u> (2):113-116, (1993)
	268	AHLNECK, et al., "The Molecular Basis of Moisture Effects on the physical and Chemical Stability of Drugs in the Solid State", State Int. J. Pharm., <u>62</u> :87-95, (1990)
	269	AKERS, et al., "Glycine Crystallization During Freezing: The Effects of Salt Form, pH, and Ionic Strength", Pharmaceutical Research, <u>12</u> (10):1457-1461, (1995)
	270	AKOH, et al., "One-stage synthesis of raffinose fatty acid polyesters", J. Food Sci., <u>52</u> (6):1570-1576, (1987)
	271	ALBERTS, et al., Molecular Biology of the Cell, 2nd ed., Garland Publishing, Inc., Ch. 2, page 58, (1989)
	272	ALDOUS, et al., "The Crystallization of Hydrates from Amorphous Carbohydrates", Cryo-Letters, <u>16</u> :181-186, (1995)
	273	ALDRICH, et al., "Use of the spinning disk technique to produce monodisperse microspheres of human serum albumin for labeling with radioisotopes", J. Applied Radiation and Isotopes, <u>25</u> :15-18, (1974)
	274	ALLEN, et al., "Determination of the Degree of Crystallinity in Solid-Solid Equilibria", J. Pharm. Sci., <u>58</u> (10):1190-1193, (1969)
	275	ALLISON, et al., "Mechanisms of Protection of Cationic Lipid-DNA Complexes During Lyophilization", Journal of Pharmaceutical Sciences, <u>89</u> (5):682-691, (2000)
	276	ALLISON, et al., Lyophilization of Nonviral Gene Delivery Systems, METHODS IN MOLECULAR MEDICINE, NONVIRAL VECTORS FOR GENE THERAPY, Ch. 18, 225-251 (Mark A. Findeis ed., Humana Press, 2001)
	277	ANCHORDOQUY, et al., Physical Stabilization of DNA Based Therapeutics, <u>6</u> (9), DDT 463-470, (May 2001)

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Other Documents

Examiner Initial	No.	Author, Title, Date, Place (e.g. Journal) of Publication
	278	ANEKWE, et al., "Relaxation Constants as a Predictor of Protein Stabilization," Biocalorimetry: Applications of Calorimetry in the Biological Science, J. E. Ladbury and B. Z. Chowdhry, editors, John Wiley & Sons, pp. 243-251, (1998)
	279	ARAKAWA, et al., "Protein-solvent interactions in pharmaceutical formulations", Pharm. Res., <u>8</u> (3):285-291, (1991)
	280	BANDARA, et al., "Intraarticular Expression of Biologically Active Interleukin IL-Receptor-Antagonist Protein by Ex Vivo Gene Transfer", <u>90</u> :10764-10768, (November 1993)
	281	BARNETT, "Exhubera Inhaled Insulin: A Review", Int. J. Clin. Pract., <u>58</u> (4):394-401, (2004)
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